

**EPA REGISTRATION FILE NUMBER  
91090-5**

# PROCESSING REQUEST

Reg # 91090-5

Decision # 510746

Description: New Basic CSF dated 10/21/2015

**Electronic Label & Letter**  
(see PPLS):

OR

**Non Electronic  
Label & Letter**  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: 10/21/2015

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Tim Ciarlo

Division: RD IVB1

Phone: 703-347-8082

Date: 8/8/2016



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:

91090-5

Date of Issuance:

08/05/16

Term of Issuance:

Conditional, Time-Limited  
Expires: 08/05/2018

Name of Pesticide Product:

Neove Spot On #003 for Cats

Name and Address of Registrant (include ZIP Code):

Ann M. Tillman  
Shanghai Neway Animal Health Co., Ltd.  
c/o Pyxis Regulatory Consulting Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 03  
Invertebrate & Vertebrate Branch 1, Registration Division (7505P)

Date:

08/05/16

2. This registration is time-limited and expires 08/05/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred (mm/dd/yyyy)
  - State in which the incident occurred (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.



- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Orders identified below:
  - a. Fipronil           GDCI-129121-1305  
                              GDCI-129121-1512

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Orders listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://www.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-pesticide-re-evaluation-division>

6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 91090-5."
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 10/21/2015

If you have any questions, please contact Tim Ciarlo by phone at 703-347-8082, or via email at [Ciarlo.Timothy@epa.gov](mailto:Ciarlo.Timothy@epa.gov).

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**Master Label:**

- 1. Carton Label (Front, back, top, bottom, right & left panels)**
- 2. Package Insert**
- 3. Label on Individual Tube**
- 4. Label on Back of Blister**
- 5. Optional Text for Carton Label/Package Insert**

**{1. Carton Label: Front Panel}**

**{Note to Reviewer: The word "Cats" will be at least 75% in height of the largest letter in the primary brand name.}**

**Neove Spot On #003 for Cats**

[Alternate Brand Names: FIPRENE PLUS FOR CATS, FIPMETH PLUS FOR CATS]

{Drawing of tube}

{Picture of appropriate size of cats}

**Kills Fleas, Flea Eggs and Larvae**

**Kills Ticks, including those that may transmit Lyme disease**

- [Fast acting]
- [Long lasting]
- [Waterproof]
- [Contains the same active ingredients used in FRONTLINE® Plus for Cats. This product is not manufactured or distributed by Merial, the maker of FRONTLINE® Plus for Cats. FRONTLINE® Plus is a registered trademark of Merial]

**ACCEPTED**

**08/05/2016**

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 91090-5

**For Use ONLY on CATS & KITTENS 8 Weeks and Older and  
Weighing Over 1.5 lbs**

**ACTIVE INGREDIENTS**

Fipronil	9.8%
(S)-methoprene	11.8%
OTHER INGREDIENTS	<u>78.4%</u>
TOTAL	100.0%

**NET CONTENT:** [X fl. oz. (Y mL)]

[[3]][4][6][8] - 0.017 fl. oz. (0.50 mL) tubes]

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{1. Carton Label: Front Panel}**

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

SEE INSERT AND BACK PANEL FOR FIRST AID AND PRECAUTIONARY STATEMENTS

**{1. Carton Label: Back Panel}**

**Neove Spot On #003 for Cats**

**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON RABBITS OR ANY OTHER ANIMALS.

Neove Spot On #003 for Cats contains fipronil and (S)-methoprene that effectively kill and control fleas and ticks for use **ONLY** on cats & kittens 8 weeks and older and weighing over 1.5 lbs.

Neove Spot On #003 for Cats remains effective after bathing, water immersion, or exposure to sunlight. Apply this product ONLY on cats/kittens 8 weeks of age or older to kill fleas, flea eggs and ticks. Do not use on cats weighing less than 1.5 lbs or younger than 8 weeks. If your cat weighs more than 20 lbs, consult with your veterinarian before use. Do not use more than one tube per cat per month, even on cats larger than 20 lbs.

**HOW TO APPLY**

- REMOVE and OPEN the child resistant package according to the instructions on package insert.
- To APPLY Neove Spot On #003 for Cats: Part the cat's hair and place the tip of the tube through the cat's hair to the skin level at the base of neck and between the shoulders. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the cat's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry.

FOR EXTERNAL USE ONLY  
DO NOT RE-APPLY FOR 30 DAYS



**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{1. Carton Label: Back Panel}**

**FREQUENCY OF APPLICATION**

**FLEAS:** When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your cat.

**TICKS:** This product kills all stages of ticks for at least one month. For best control of ticks, apply once every month.

**Side Effects:** Monitor your cat after application. Cats may experience some temporary irritation at the site of application. If signs persist or become more severe with a few days of application, consult a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

**FOR CAT USE ONLY**

If ingested by a cat, contact your veterinarian immediately.

Made in [China]

**SHANGHAI NEWAY ANIMAL HEALTH CO., LTD**

[PRODUCT BAR CODE]

RM509, 1438 Shan Xi Bei Road,

Shanghai, 200060

P. R. China

All rights reserved.

EPA Reg. No.: 091090-

EPA Est. No.:

**{1. Carton Label: Top, Left and Right Panels}**

Neove Spot On #003 for Cats

{Drawing of tube}

For Use ONLY on **CATS and KITTENS 8 Weeks or Older and Over 1.5 lbs**

**{1. Carton Label: Bottom Panel}**

For Cat Use Only

Lot/Batch No.: XXXXXX

**{2. Package Insert}**

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**Neove Spot On #003 for Cats**

**READ ENTIRE LABEL BEFORE EACH USE**

**USE ONLY ON CATS & KITTENS OVER 8 WEEKS OF AGE OR OLDER AND  
WEIGHING OVER 1.5 LBS**

Neove Spot On #003 for Cats provides a fast-acting, long-lasting and waterproof treatment to:

- Kill Fleas, Flea Eggs and Larvae
- Kill Ticks, including those that may transmit Lyme disease and other tick-borne diseases

**ACTIVE INGREDIENTS**

Fipronil	9.8%
(S)-methoprene	11.8%
OTHER INGREDIENTS	<u>78.4%</u>
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

**FIRST AID**

<b>If Swallowed</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor for treatment advice immediately</li><li>• Have person sip a glass of water if able to swallow</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor</li><li>• Do not give anything to an unconscious person</li></ul>
<b>If in Eyes</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice</li></ul>
<b>If on Skin</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water and soap for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
Hotline Number: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Call 1-XXX-XXX-XXXX for emergency treatment information.	

**PRECAUTIONARY STATEMENTS**

**HAZARDS TO HUMANS - CAUTION**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

{2. Package Insert}

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**HAZARDS TO DOMESTIC ANIMALS**

**FOR EXTERNAL USE ONLY.** Do NOT use on kittens under 8 weeks of age or weighing less than 1.5 lbs. Do NOT use on rabbits or any other animals. Sensitivities, while rare, may occur after using ANY pesticide product for pets. If signs persist, or become more severe, consult a veterinarian immediately. Certain medications can interact with pesticides. Consult a veterinarian before using on medicated, debilitated or aged cats.

**Side Effects:** Monitor your cat after application. Cats may experience some temporary irritation at the site of application. If signs persist or become more severe within a few days of application, consult a veterinarian immediately. If your cat has an unusual reaction to the initial application, consult a veterinarian before repeating treatment.

**PHYSICAL OR CHEMICAL HAZARDS**

**Flammable:** Keep away from heat or open flame.

Do not mix or allow to come into contact with oxidizing agents. Hazardous chemical reaction may occur.

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{2. Package Insert}**

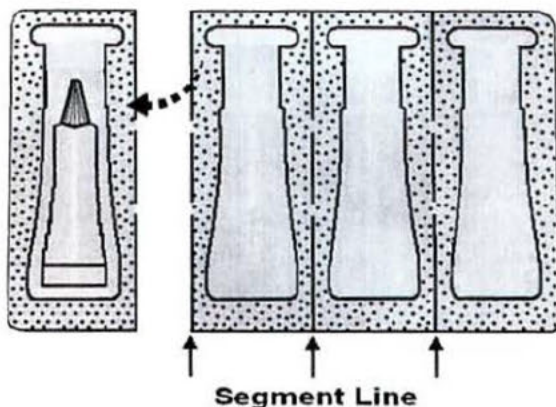
**DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **Do not allow children to apply product.** TO PREVENT HARM TO YOU AND YOUR CAT, READ ENTIRE LABEL AND PACKAGE INSERT BEFORE EACH USE. FOLLOW ALL DIRECTIONS AND PRECAUTIONARY STATEMENTS CAREFULLY. USE ON CATS ONLY AND DO NOT ALLOW YOUR CAT TO INGEST THIS PRODUCT. DO NOT USE ON RABBITS OR ANY OTHER ANIMALS.

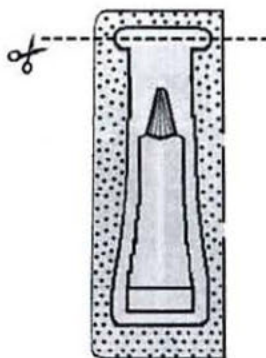


**HOW TO REMOVE AND OPEN THE CHILD RESISTANT PACKAGE**

1. Snap off **ONE** blister pack along the segment line.



2. Use scissors to cut across the top bubble section (Do not harm the tube inside).



3. Peel off the foil from the cut line and take out the tube.

**{2. Package Insert}**



## **HOW TO APPLY**

Remember, your cat needs to be dry at the time when this product is applied and must remain dry for 24 hours after application.

1. Hold the tube in an upright position facing away from you and your cat's face and eyes. Screw the cap off the tube.
2. The cat should be standing for easy application. Part the cat's hair and place the tip of the tube through the cat's hair to the skin level at the base of neck and between the shoulders. Squeeze the tube thoroughly to ensure the entire contents are applied in a single spot on the cat's skin. Do not apply the product superficially to the hair coat and avoid contact with the treated area until dry. Do not use more than one tube per cat per month, even on cats larger than 20 lbs.

*[ Visual Depicting Application To Cats ]*

3. Make sure the tube is empty after application and discard empty tube as described in the Storage and Disposal section.

## **FREQUENCY OF APPLICATION**

**FLEAS:** When used monthly, this product breaks the flea life cycle and controls flea, flea eggs, and flea larvae on your cat.

**TICKS:** This product kills all stages of ticks for at least one month. For best control of ticks, apply once every month.

## **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**Pesticide Storage:** Store unused tubes in the original child-resistant package; keep out of reach of children and animals.

### **Pesticide Disposal:**

If Partly Filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**Container Handling:** Non-refillable container. If Empty: Do not reuse or refill the container. Place in trash or offer for recycling if available.

## **WARRANTY**

To the extent consistent with applicable law, Sellers makes no warranty, express or implied, concerning the use of this product other than as indicated on the labeling. Buyer assumes all risk of use and handling of the product when such use and handling are contrary to the label instructions.

## **USE ON CATS ONLY**

**SHANGHAI NEWAY ANIMAL HEALTH CO., LTD**

**All rights reserved.**

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{3. Label on Individual Tube}**

**Neove Spot On #003 for Cats**

9.8% Fipronil  
11.8% (S)-methoprene

0.017 fl. oz. (0.5 mL)

**ONLY for CATS & KITTENS 8 Weeks or Older and Over 1.5 lbs**

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

Read entire label before each use

[NEWAY]

EPA Reg. No.: 091090-

Lot No.: 0000000

**Neove Spot On #003 for Cats  
MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{4. Label on Back of Blisters}**

**Neove Spot On #003 for Cats**

9.8% Fipronil  
11.8% (S)-methoprene

0.017 fl. oz. (0.5 mL)

**ONLY for CATS & KITTENS 8 Weeks or Older and Over 1.5 lbs**

KEEP OUT OF REACH OF CHILDREN

**CAUTION**

Read entire label before each use

[NEWAY]

EPA Reg. No. 091090-  
[Lot No. 0000000]

**Neove Spot On #003 for Cats**  
**MASTER LABEL**

Note: [Brackets indicate alternate language] and  
{braces indicate notes to review}.

**{5. Optional Text for Carton Label/Package Insert}**

{NON-PESTICIDE RELATED TEXT}

- [Buy "X" get "Y" free]
- [X% more free]
- [[Value Pack][Great Value][Bonus Pack]]
- [[Convenient/Easy] to use]
- [[X] month supply]
- [Best results when used monthly (30 days)]
- [Remains effective after [bathing][swimming][exposure to sunlight]]
- [Apply directly to your cat's skin]

{PESTICIDE RELATED TEXT}

- [Provides [Easy], [Fast] and [effective] control of flea and tick for cats & kittens]
- [Effective monthly treatment of [fleas] and [ticks]]
- [Monthly [flea] and [tick] protection]
- [[Prevents] all stages of flea [eggs, larvae, pupae] from developing]
- [Effective [against] all stages of the flea life cycle]
- [Controls flea reinfestation]
- [Contains (S)-methoprene, an Insect Growth Regulator which breaks flea life cycle]
- [[Breaks] the flea life cycle]
- [Dual action: Fipronil & (S)-methoprene IGR]
- [A once a month application may be needed if cat is at a high risk for flea reinfestation]
- [[Kills] ticks that may transmit [Lyme disease], [haemobartonellosis], [babesiosis], [ehrlichiosis], [anaplasmosis] and other tick-borne diseases]
- [Kills ticks for up to [4 weeks][1 month][30 days]]





United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 91090	2. EPA Product Manager M. Echeverria	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Shanghai Neway Animal Health Co., Ltd./Neove Spot On #003 for Cats	PM# IVB 1	
5. Name and Address of Applicant (Include ZIP Code) Shanghai Neway Animal Health Co., Ltd., c/o Pyxis Regulatory Consulting Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 65331-4 Product Name Frontline Plus for Cats	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application falls under PRIA Category R315 (48: New end-use non-food animal product with registered sources of active ingredients). The fee is \$8,820 but Shanghai Neway qualifies for a 75% small business waiver. The fee of \$2,250 has been paid.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.05, 0.068, 0.1, 0.136 fl oz	No. per container 3, 4, 6, 8	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 0.017 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other on box and on insert in box	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ann M. Tillman		Title Agent		Telephone No. (Include Area Code) (253) 853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Agent			
4. Typed Name Ann M. Tillman		5. Date Oct. 29, 2015			

PYXIS REGULATORY CONSULTING, INC.

4110 136<sup>th</sup> St. CT NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

October 29, 2015

MRID 49445400

ELECTRONIC DELIVERY

Marietta Echeverria, Branch Chief  
Invertebrate-Vertebrate Branch 1  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Shanghai Newway Animal Health Co., Ltd.  
Neove Spot On #003 for Cats (EPA File Symbol 91090- )  
Application for New Pesticide Registration  
PRIA Category R315

Dear Ms. Echeverria,

On behalf of Shanghai Newway Animal Health Co., Ltd. (SNAH), we are submitting an application for registration of Neove Spot On #003 for Cats, an end use product containing the active ingredients fipronil and S-methoprene.

In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Proposed Labeling for Neove Spot On #003 for Cats
4. Formulator's Exemption Statement (EPA Form 8570-27)
5. Certification with Respect to Citation of Data (EPA Form 8570-34)
6. Agency Internal Use Copy of the Data Matrix (EPA Form 8570-35)
7. Public File Copy of the Data Matrix (EPA Form 8570-35)
8. Child Resistant Packaging Certification for NW-Tube-1
9. Signed Small Business Waiver request for this action
10. Signed Small Business certification for this action
11. Copy of the PRIA payment from pay.gov
12. Letter of Authorization
13. Product Specific Data:

MRID	Volume	Guideline	Report Title
49445401	Volume 1	830.1550, 830.1600, 830.1650, 830.1670, 830.1750	Zhao, J. and Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Formulation Process, Discussion of the Formation of Impurities, and Certified Limits for Neove Spot On #003 for Cats. <i>Contains Confidential Business Information.</i>



MRID	Volume	Guideline	Report Title
49445402	Volume 2	830.1800	Tao., Z. Enforcement Analytical Methods Validation for Neove Spot On #003 for Cats.
49445403	Volume 3	Group B 830 Series	Tillman, A. M. Group B Self-Certification of Physical/Chemical Properties for Neove Spot On #003 for Cats.
49445404	Volume 4	870.1300	Tillman, A. M. Neove Spot On #003 for Cats: Waiver Request for Acute Inhalation Toxicity Data.

SNAH submitted CRP data with the application for registration of Neove Spot On #003 for Dogs (EPA File Symbol 91090-pending). The references for these studies are listed below.

49729704	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Child Panel NW-TUBE-1.
49729705	US 16 CFR § 1700	Dixon, L. M. Child-Resistant Protocol Test Senior Panel NW-TUBE-1.

Please note that SNAH conducted CRP testing (CRE and SAUE) with one tube size (NW-Tube-1); 4 blisters connected together) filled with placebo water (0.045 fl. oz.). Based on conversations between Maggie Rudick and SNAH, the CRP testing was designed so that the data for this fill volume, the maximum volume to be added to this tube, could be used to bridge to other fill volume for this product, i.e., 0.017 fl. oz. SNAH will package one or two sets of four blisters or one or two sets of three blisters in cartons (total number of units: 3, 4, 6 or 8). SNAH believes that the CRP data can be bridged to the fill volume of 0.017 fl. oz., and to packages containing three blisters, and to packages containing a total of 6 or 8 units. The CRP results showed that this package meets the standards of 40 CFR 157.32(a).

SNAH's Neove Spot On #003 for Cats qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements. SNAH is using the selective method of data support for certain product specific data. As per EPA's interpretations of 40 CFR Parts 152.90 - 152.96, SNAH submitted notices of intent to apply and offers to pay to the extent required by FIFRA § 3(c)(1)(F).

This application falls under Category R315 (48: New end use non-food animal product). The PRIA fee is \$8,820 but SNAH qualifies for a 75% small business waiver. The fee of \$2,205 has been paid.

We trust you will find this application complete. However, please feel free to contact me by email at [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com) or by phone at (253) 853-7369 if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

**NEWAY**

October 13, 2015

Document Processing Desk (COADR)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

To Whom It May Concern:

RE: Letter of Authorization

Please let this letter serve to notify you that Pyxis Regulatory Consulting, Inc. is authorized to represent Shanghai Neway Animal Health Co., Ltd. (EPA Company Number 91090 ) before the US Environmental Protection Agency in all matters regarding our pesticide producing establishment registration, Neove Spot On #003 for Dogs and Neove Spot On #003 for Cats registrations and applications for registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 USC Section 136 et seq.

If you have any questions, please do not hesitate to contact me.

Sincerely,

  
Zane Liu  
President

cc: Janelle Kay; Pyxis Regulatory Consulting, Inc.

---

**Shanghai Neway Animal Health Co., Ltd.**

Rm 509, 1438 Shan Xi Bei Rd, Shanghai, China, 200060

Tel: 86 21 5187 7909

Fax: 86 21 6148 4508

Website: [www.newaypharm.com.cn](http://www.newaypharm.com.cn)

**DOCUMENTUM**




## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

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## DATA MATRIX


Date <b>October 29, 2015</b>			EPA Reg. No./File Symbol <b>91090-</b>		Page <b>1</b> of <b>4</b>
Applicant's/Registrant's Name & Address <b>Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332</b>			Product <b>Neove Spot On #003 for Cats</b>		
Ingredient <b>Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition	49745401	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1600	Description of Materials Used to Produce the Product	49745401	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1620	Description of Production Process				Not required <sup>1</sup>
830.1650	Description of Formulation Process	49745401	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1670	Discussion of Formation of Impurities	49745401	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1700	Preliminary Analysis				Not Required <sup>2</sup>
830.1750	Certified Limits	49745401	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.1800	Enforcement Analytical Method	49745402	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6302	Color	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6303	Physical State	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6304	Odor	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions				Not Required <sup>3</sup>
830.6314	Oxidation/Reduction: Chemical Incompatibility	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6315	Flammability	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
Signature 			Name and Title <b>Ann M. Tillman, Consultant</b>		Date <b>Oct. 29, 2015</b>

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## DATA MATRIX

Date October 29, 2015		EPA Reg. No./File Symbol 91090-		Page 2 of 4	
Applicant's/Registrant's Name & Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332		Product Neove Spot On #003 for Cats			
Ingredient Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6316	Explosibility	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	Waiver <sup>4</sup>
830.6317	Storage Stability	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6319	Miscibility				Not required <sup>5</sup>
830.6320	Corrosion Characteristics	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.6321	Dielectric Breakdown Voltage				Not required <sup>6</sup>
830.7000	pH	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7050	UV/Visible Absorption				Not Required <sup>7</sup>
830.7100	Viscosity	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7200	Melting Point/Melting Range				Not Required <sup>7</sup>
830.7220	Boiling Point/Boiling Range				Not Required <sup>7</sup>
830.7300	Density/Relative Density/Bulk Density	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	
830.7370	Dissociation Constants in Water				Not Required <sup>7</sup>
830.7520	Particle size, fiber length, diameter distribution	49745403	Shanghai Neway Animal Health Co., Ltd.	OWN	Waiver <sup>8</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Not Required <sup>7</sup>
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7560
Signature 			Name and Title Ann M. Tillman, Consultant		Date Oct. 29, 2015

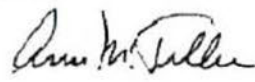


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## DATA MATRIX

Date <b>October 29, 2015</b>		EPA Reg. No./File Symbol <b>91090-</b>		Page <b>3</b> of <b>4</b>	
Applicant's/Registrant's Name & Address <b>Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW, Gig Harbor, WA 98332</b>		Product <b>Neove Spot On #003 for Cats</b>			
Ingredient <b>Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7560
830.7840	Water Solubility: Column Elution Method; Shake Flask Method				Not Required <sup>7</sup>
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure				Not Required <sup>7</sup>
870.1100	Acute Oral Toxicity: Rat	44942004		OLD	
870.1200	Acute Dermal Toxicity: Rat	44942005		OLD	
870.1300	Acute Inhalation Toxicity: Rat	49745404	Shanghai Neway Animal Health Co., Ltd.	Waiver	See endnote <sup>9</sup>
870.2400	Primary Eye Irritation: Rabbit	44942006		OLD	
870.2500	Primary Dermal Irritation	44942007		OLD	
870.2600	Dermal Sensitization	44942008		OLD	
870.7200	Companion Animal Safety	44942009		OLD	
Signature 			Name and Title <b>Ann M. Tillman, Consultant</b>		Date <b>Oct. 29, 2015</b>

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date <b>October 29, 2015</b>		EPA Reg. No./File Symbol <b>91090-</b>		Page <b>4</b> of <b>4</b>	
Applicant's/Registrant's Name & Address  <b>Shanghai Neway Animal Health Co., Ltd.</b> <b>c/o Pyxis Regulatory Consulting, Inc.</b> <b>4110 136th St. NW,</b> <b>Gig Harbor, WA 98332</b>		Product  <b>Neove Spot On #003 for Cats</b>			
Ingredient <b>Fipronil (CAS No. 120068-37-3) and S-methoprene (CAS No. 65733-16-6)</b>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>810.3300</b>	<b>Product Performance</b>	<b>44942020</b>		<b>OLD</b>	
		<b>44942011</b>		<b>OLD</b>	
		<b>43121115</b>		<b>OLD</b>	
		<b>43121117</b>		<b>OLD</b>	
		<b>43121118</b>		<b>OLD</b>	
		<b>43121122</b>		<b>OLD</b>	
<b>US 16 CFR § 1700</b>	<b>Child Resistant Packaging Study</b>	<b>49729704</b>	<b>Shanghai Neway Animal Health Co., Ltd.</b>	<b>OWN</b>	
		<b>49729705</b>	<b>Shanghai Neway Animal Health Co., Ltd.</b>	<b>OWN</b>	
<b>Generic Data Requirements</b>					
Shanghai Neway Animal Health Co., Ltd.'s Neove Spot On #003 for Cats qualifies for the Formulator's Exemption for fipronil and S-methoprene generic data requirements.					
Signature  			Name and Title <b>Ann M. Tillman, Consultant</b>		Date <b>Oct. 29, 2015</b>



## Endnotes for Data Matrix for Neove Spot On #003 for Cats

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- <sup>1</sup> **830.1620** - These data are not required for the registration of an end-use product. See 830.1650 for formulation process information.
- <sup>2</sup> **830.1700** – This product does not consist solely of the technical grade active ingredient (TGAI) and is not produced by an integrated system, therefore, per OPPTS 830.1700, these data are not required.
- <sup>3</sup> **830.6313** – These data are not required for registration of an end-use product.
- <sup>4</sup> **830.6316** – Neither the active ingredients, fipronil or S-methoprene, nor any of the inert ingredients in Neove Spot On #003 for Cats contains the chemical bonds or functional groups associated with chemicals that are explosive. Therefore, a waiver from this data requirement is requested.
- <sup>5</sup> **830.6319** - This data requirement is required when the product is an emulsifiable liquid and to be diluted with petroleum solvents. Neove Spot On #003 for Cats is not an emulsifiable liquid to be diluted with petroleum solvents and therefore this data requirement is not applicable.
- <sup>6</sup> **830.6321** - This product is not proposed for use around electrical equipment. Therefore, these data are not applicable.
- <sup>7</sup> **830.7050, 830.7200, 830.7220, 830.7370, 830.7550-7570, 830.7840-7860, 830.7950** – These data are not required for registration of an end-use product.
- <sup>8</sup> **830.7520** – Shanghai Neway Animal Health Ltd. is seeking a waiver for this data requirement for Neove Spot On #003 for Cats because the product is not a fibrous material or a water-insoluble material.
- <sup>9</sup> **870.1300** – A waiver from the requirement of an acute inhalation toxicity study is requested for this formulation. Based on the use pattern (a spot-on treatment for domestic animals), inhalation is not expected to be a significant route of exposure. EPA has previously waived this requirement for similar use products.



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**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Shanghai Neway Animal Health Co., 4110 136th St. Ct. NW; Gig Harbor, WA 98332; 253-853-7369	EPA Registration Number/File Symbol 91090-
Active Ingredient(s) and/or representative test compound(s) Fipronil, S-Methoprene	Date Oct. 29, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor nonfood	Product Name Nevee Spot On #003 for Cats

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature   
 Digitally signed by Ann M. Tillman  
 DN: cn=Ann M. Tillman, o=Pyxis  
 Regulatory Consulting, Inc., ou=Pyxis,  
 email=Ann@PyxisRC.com, c=US  
 Date: 2015.10.29 06:45:07 -04'00'

Date  
Oct. 29, 2015

Typed or Printed Name and Title  
Ann M. Tillman, Agent





United States  
**Environmental Protection Agency**  
 Washington, DC 20460  
**Formulator's Exemption Statement**  
 (40 CFR 152.85)

Applicant's Name and Address Shanghai Neway Animal Health Co., Ltd. c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332	EPA File Symbol/Registration Number 91090-
	Product Name Neove Spot On #003 for Cats
	Date of Confidential Statement of Formula (EPA Form 8570-4) 10/21/2015

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Fipronil  
 (S)-methoprene

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

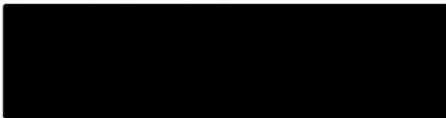
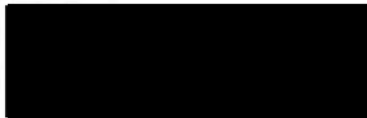
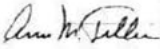
(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Fipronil (S)-methoprene  <small>Digitally signed by Ann M. Tillman            DN: cn=Ann M. Tillman,            o=Pyxis Regulatory            Consulting, Inc., ou=Pyxis,            email=Ann@PyxisRC.com,            c=US            Date: 2015.10.29 06:44:16            +04'00'</small>		
<p><b>*Product ingredient source information may be entitled to confidential treatment*</b></p>		
Signature 	Name and Title Ann M. Tillman, Agent	Date 10/29/2015

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
 Copy 2 - Applicant copy

DOCUMENTUM



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 3, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-510746  
EPA File Symbol or Registration Number: 91090-L  
Product Name: Neove Spot On #003 for Cats  
EPA Receipt Date: 30-Oct-2015  
EPA Company Number: 91090  
Company Name: SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

ANN M. TILLMAN  
PYXIS REGULATORY CONSULTING, INC.  
SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.  
4110 136TH ST. CT., NW  
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Application and 75% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 75% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY;;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in dark ink, appearing to be "mizh".

Front End Processing Staff  
Information Technology & Resources Management Division



**Ann Tillman**

---

**From:** notification@pay.gov  
**Sent:** October 30, 2015 6:39 AM  
**To:** Ann Tillman  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25O5TNKQ  
Agency Tracking ID: 74899720957  
Transaction Type: Sale  
Transaction Date: 10/30/2015 06:39:09 AM EDT

Account Holder Name: Ann Tillman

Transaction Amount: \$2,205.00  
Billing Address: 4110 136th St. CT NW  
Billing Address 2:  
City: Gig Harbor  
State/Province: WA  
Zip/Postal Code: 98332  
Country: USA  
Card Type: [REDACTED]  
Card Number: [REDACTED]

Registration Number:  
Company Name: Shanghai Neway Animal Hea  
Company Number: 91090  
Action Code: R315

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

DOCUMENTUM

**Receipt for Section 3**

S: 976473

Milestone Email: Ann@PyxisRC.com

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Company: 91090 SHANGHAI NEWAY ANIMAL HEALTH CO., LTD.

Billable: ☒ Yes ☐ No

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 3

Product #: 91090-L Product Name: Neove Spot On #003 for Cats

Override#:

Me Too Section3: 65331-4 Me Too Product Name: FRONTLINE PLUS FOR CATS

Application Date: 29-Oct-2015

OPP Rec'd Date: 30-Oct-2015

Front End Date: 30-Oct-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description: Portal submission # 8914. Application for registration of new product.

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Receipt Content

Study

CSF

View/Edit

New Ingredient Request Date:

New Ingredient Received Date:

DOCUMENTUM

7

**Fee for Service**

{976473B~

This package includes the following

- ☒ New Registration
- ☐ Amendment

☒ Studies?      ☒ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.    3

Receipt No.	S-	<span style="border: 1px solid black; padding: 2px 20px;">976473</span>
EPA File Symbol/Reg. No.		<span style="border: 1px solid black; padding: 2px 20px;">91090-L</span>
Pin-Punch Date:		<span style="border: 1px solid black; padding: 2px 20px;">10/30/2015</span>

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R315  
Granted: R315 (W)  
Amount Due: \$ 8800

Parent/Child Decisions:

☒ Inert Cleared for Intended Use      ☐ Uncleared Inert in Product

Reviewer: \_\_\_\_\_ Date: 11/2/15

Remarks: *Coded in*  
*Documentum*  
**DOCUMENTUM**



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-30-15

Experts In-Processing Signature: B.B.

Date 11-3-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>91090-L</u>		EPA Receipt Date: <u>10-30-15</u>							
Items for Review			Yes	No	N/A*				
1	Application Form (EPA Form 8570-1) signed & complete including package type		X						
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X						
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		X						
	Certificate and data matrix consistent		X						
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no					
yes	no								
	If applicable, is there a letter of Authorization for exclusive use only.								
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)		X						
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		X						
5	a) Selective Method (Fee category experts use)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td style="text-align: center;">X</td> <td></td> </tr> </table>	yes	no	X				
yes	no								
X									
b) Cite-All (Fee category experts use)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no						
yes	no								
c) Applicant owns all data (Fee category experts use)	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="text-align: center;">yes</td> <td style="text-align: center;">no</td> </tr> <tr> <td></td> <td></td> </tr> </table>	yes	no						
yes	no								
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)		X						
7	Is the data package consistent with PR Notice 86-5		X						
8	Notice of Filing included with petitions				X				



9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

\* Documentation: Pass / Fail

- required forms are complete

\* Inserts: Pass / Fail

- insert not listed in the database.
- contacted the submission on 11-3-15
- received the revised CSF on 11-3-15
- Inserts approved for non-food use

\* PRN 11-3: Pass / Fail

MRZD: 497454

\* Overall Status: Pass / Fail

JR 11-10-15

## Kang, Ji Yeon

---

**From:** Ann Tillman <Ann@PyxisRC.com>  
**Sent:** Tuesday, November 03, 2015 2:56 PM  
**To:** Kang, Ji Yeon  
**Cc:** Ashe, Anthony  
**Subject:** RE: Submission to EPA: Neove Spot On #003 for Cats (EPA Reg. No. 91090-L)  
**Attachments:** 20151021 Neove Spot On #003 Cats CSF\_R1.pdf

Hi, Joyce,

The revised CSF is attached. I made a similar change for a similar product (Neove Spot On #003 for Dogs (91090-U)) at the request of Stephanie Varner. Please let me know if you need anything further.

Ann

*Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)*

**From:** Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]  
**Sent:** November 03, 2015 2:43 PM  
**To:** Ann Tillman <Ann@PyxisRC.com>  
**Cc:** Ashe, Anthony <Ashe.Anthony@epa.gov>  
**Subject:** Submission to EPA: Neove Spot On #003 for Cats (EPA Reg. No. 91090-L)

Dear Ms. Tillman,

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submissions in support of the product Neove Spot On #003 for Cats (EPA Reg. No. 91090-L). We have found few deficiencies with the submissions that will need to be addressed:

1. There is an issue with inert ingredient listed on the CSF. Please see attached Inert Clearance Status Forms for more information

Please send the necessary documents before Nov 17<sup>th</sup> so that we may further process your submission. After Nov 17<sup>th</sup>, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Best,

Joyce Kang

Contractor, US EPA  
2777 S. Crystal Drive, S-4822  
Arlington, VA 22202  
(703) 347-0416



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**Date:** June 28, 2016

**SUBJECT:** Neove Spot On #003 for Cats. Child Resistant and Senior Adult Use Effectiveness Packaging Evaluation for Child Resistant Packaging (CRP)

**Registration No.:** 91090-L

**PC Code:** 129121, 105402

**Chemical Names:** Fiprill (9.8%) and S-Methoprene (11.8%)

**Product Type.:** Spot On

**ASTM Classification:** 8F

**CR Packaging Manufacturer:** Sichuan HuiLi Industry Co. LTD

**Decision No.:** 510746

**DP Barcode:** 430948

**Regulatory Action.:** Child Resistant and Senior Adult Use Effectiveness Testing

**MRID No.:** 49729704 and 49729705

**40 CFR:** 40 CFR Part 157

**Fill Volumes:** 0.045 fl. oz. (1.34 ml)

**FROM:** Lisa Pahel, CR/SAUE Primary Reviewer  
Fungicide & Herbicide Branch  
Registration Division (RD)

**THROUGH:** Lindsay Roe, Biologist  
Fungicide Branch  
Registration Division (RD)

**TO:** Timothy Ciarlo, Risk Manager  
Kable Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (RD)

**Introduction**

The Registration Division (RD) of the Office of Pesticide Programs (OPP) has requested that the CRP team screen the child resistant effectiveness (CRE) and senior adult use effectiveness (SAUE) study data submitted under the Pesticide Registration Improvement Act (PRIA). The CRP team has reviewed the data submitted in support of the new packaging design to house the subject product.

**CRE Study Results Summary for Short tube CR-blister pack, 1.34 ml**

<b><u>40 CFR 157.32 Requirements</u></b>	<b><u>Study Results</u></b>	<b><u>Acceptability</u></b> A = acceptable U = unacceptable
<b>Failure level</b>	Access to inside of the package was considered a failure	A
<b>Child received</b>	At the beginning of each test period, the child received 1 card containing four tubes	A
<b>Age and Gender distribution for children</b>	50 children (The difference between the number of boys and the number of girls in each age range shall not exceed 10% of the number of children in that range.) Age 42-44 months 30% Age 45-48 months 40% Age 49-51 months 30%	A
<b>Access rate</b> (Must be greater than 94% in the first 5 min. & 90% after 10 min.)	0 children accessed contents of card before demonstration 3 children accessed contents of card after demonstration 3 children accessed contents of card during the test  First five minutes (before demo): 100% Effectiveness Full ten minutes (after demo): 94% Effectiveness	A
<b>Sites</b>	No site was used more than 20% of the time.	A
<b>Testers</b>	No single tester tested more than 30% of the panel.	A
<b>Tamper Resistant Features</b>	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A
<b>Outer packaging</b>	Outer packaging is not given to the child.	A
<b>Handicaps</b>	No child should have an overt physical or mental handicap.	A
<b>Groups and Familiarity</b>	Children divided into groups of two and testing administered in a familiar environment to the children.	A
<b>Dialogue</b>	Script outlined in 16 CFR 1700.20 followed by tester.	A
<b>Findings</b>	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A



<b>Data collected and verified by:</b>	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A
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#### SAUE Study Results Summary for Short tube CR-blister pack, 1.34 ml

<b><u>40 CFR 157.32 Requirements</u></b>	<b><u>Study Results</u></b>	<b><u>Acceptability</u></b> A = acceptable U = unacceptable
<b>Failure level</b>	Inability to open the package within the 5-min test period or unable to open and properly re-secure the package during the 1-minute test period was considered a failure	A
<b>Tester received</b>	At the beginning of each test period, the tester received 1 card containing four tubes	A
<b>Age and Gender distribution for adults</b>	50 senior adults Age 50-54 years - 25% (8 males, 17 females) Age 55-59 years - 25% (7 males, 18 females) Age 60-70 years - 50% (15 males, 35 females)	A
<b>Access rate</b> (Must be 90% or greater)	1 adults failed to open the package within the 5-min. test 1 adults failed to open the package within the 1-min test <hr/> 2 total failures 98% Senior Adult Use Effectiveness	A
<b>Sites</b>	No site was used more than 24% of the time.	A
<b>Testers</b>	No single tester tested more than 35% of the panel.	A
<b>Tamper Resistant Features</b>	Tamper resistant features of the package have been removed prior to testing unless it is part of the CRP.	A
<b>Outer packaging</b>	If the outer package gives the instructions for how to open the CRP, the CRP should be given to the test subject in the packaging. If the outer package does not give instructions	A

	relevant to the test, the outer package will not be given to the test subject.	
<b>Handicaps</b>	No adult should have an overt physical or mental handicap, permanent or temporary illness, or injury which would interfere with his/her effective participation shall be included in the test.	A
<b>Dialogue</b>	Script outlined in 16 CFR 1700.20 followed by tester.	A
<b>Findings</b>	This analysis shows that the package described herein meets the requirements of 40 CFR Part 157.	A
<b>Data collected and verified by:</b>	Great Lakes Marketing Research 3361 Executive Parkway, Suite 200 Toledo, OH 43606	A

### Package and Testing Description

Container: NW-TUBE-1

Short tube CR-blister pack, filled 1.34 ml

- Material: PET/PE Plastic & Colorless (transparent)
- Manufacturer: Sichuan HuiLi Industry Co. LTD
- Size/Shape: Blister pack

Sealing Film

- Material: PET/PA/AL/PE & Silver color, liner material= polyamide and aluminum

Package Contents: The package was filled with a placebo and sealed with a heat seal by Shanghai Neway Animal Health Co., LTD

### Conclusion

Based on the submitted data reviewed herein, all CRE and SAUE testing data requirements have been fulfilled for the proposed blister pack filled with 1.34 ml filled tube.

The data matrix should always include MRIDs 49729704 and 49729705 fulfill CR data

requirement.

### **Label Revisions**

Directions for opening the package must be included on the product label and must exactly match those found on page 20 of MRID 49729705. The label language as submitted with this data package is acceptable.



**FEE**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D 430931; **FILE SYMBOL No:** 91090-L; **PRODUCT NAME:** Neove Spot On #003 for Cats; **DECISION No.:** 510746; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

**DATE OUT:** 05/02/16

**SUBJECT:** End Use Product Chemistry Review  
Product Name: Neove Spot On #003 for Cats

**FROM:** Indira Gairola / Product Chemistry Team  
CITAB/RD (7505P)

**TO:** Timothy Ciarlo / Kable Davis, RM 03  
IV Branch1 / RD (7505P)

05/05/16  
SJB  
5/5/16

**INTRODUCTION:**

The registrant has submitted an application for the registration of the new end use product "Neove Spot On #003 for Cats". In support of the registration application, the registrant submitted 830 series group product chemistry data with MRID No's. 497454-01 to-03 for group A and submitted self-certification for group B. CITAB has been asked to determine acceptability of the data cited and the proposed Basic CSF(s) dated 10/2/15.

**SUMMARY OF FINDINGS:**

1. Name of Active Ingredient(s): Fipronil (9.8%) and (S)-Methoprene (11.80%)
2. Has the registrant claimed substantial similarity to a registered product?  
[ ] Yes; [x] No; [ ] NA; if yes give the registration number of the cited product.
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes [ ] No
4. All inert ingredients have been screened by CITAB (Inert Team) and found to be approved for the proposed label uses - [x] Yes; [ ] No.

**DP BARCODE No.:** D 430931; **FILE SYMBOL No:** 91090-L; **PRODUCT NAME:** Neove Spot On #003 for Cats; **DECISION No.:** 510746; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Neway Animal Health Co., Ltd

5. Confidential Statement of Formula(s):

☒ Basic - Dated: 10/21/15 Re-submitted – ☐ NA

☐ Alternate Re-submitted – Dated: ☒ NA

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

- a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☒ Yes, if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☐ Yes; ☐ No; if not, explain below

Metallic equivalent: ☐ Yes ☒ NA;

Soluble arsenic: ☐ Yes ☒ NA

Isomeric ratios: ☐ Yes ☒ NA

Acid Equivalent: ☐ Yes ☒ NA; acid equivalent =

- b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes; ☐ No; ☒ NA

Methanol at > 4%: ☐ Yes; ☐ No; ☒ NA

Sodium nitrate/sodium nitrite ☐ Yes; ☐ No; ☒ NA

- c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☒ Yes ☐ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes; ☐ No; ☒ NA; if not, explain below

- d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

**DP BARCODE No.:** D 430931; **FILE SYMBOL No:** 91090-L; **PRODUCT NAME:** Neove Spot On #003 for Cats; **DECISION No.:** 510746; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Neway Animal Health Co., Ltd

7. Group A: Product Chemistry Data

CITAB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos. Cited
			Yes	No		
830.1550	Product Identity & Composition				A	497454-01
830.1600	Description of materials used to produce the product		x		A	497454-01
830.1650	Description of formulation process		x		A	497454-01
830.1670	Discussion on the formation of impurities		x		A	497454-01
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified limits	x			CSF dated 10/21/16 497454-02 Validated method was provided
		Proposed Limits				
		Justification for wider limits			A	
830.1800	Enforcement analytical method <sup>1</sup>		x		A	

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable.

1. If validation of analytical method is not provided, the data requirements should be "N" (Not Acceptable)



**DP BARCODE No.:** D 430931; **FILE SYMBOL No:** 91090-L; **PRODUCT NAME:** Neove Spot On #003 for Cats; **DECISION No.:** 510746; **PC Code(s):** 105402, 129121; **ACTION CODE:** R315; **FOOD Use:** No; **COMPANY:** Shanghai Newway Animal Health Co., Ltd

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos.
830.6303	Physical State	Clear, slightly viscous liquid	A	497454-03
830.6314	Oxidation/Reduction	Compatible with water, ammonium phosphate, iron powder, turpentine. Incompatible with 5% potassium permanganate;	A	497454-03
830.6315	Flammability	Flash point 38.2°C (Pensky-Martens closed cup Method)	A	497454-03
830.6316	Explodability	This product does not contain explosive material	W	497454-03
830.7000	pH	7.4 (25 °C; 1% aq.; pH of wa aq.; pH of water 5.40)	A	497454-03
830.7100	Viscosity	12.9 cP (mPa s; 20 °C) and 78.5 cP (mPa s; 40°C);	A	497454-03
830.7300	Density (units)	1.02 g/mL (25°C; pycnometer)	A	497454-03
830.6317	Storage stability Or Accelerated storage stability	Stable at normal and elevated temperatures. Day 0: Fipronil 9.86%, S-methoprene 12.2% Day 14, 54°C: Fipronil 9.81%, S-methoprene 12.1%	A	497454-03
830.6320	Corrosion characteristics or Accelerated corrosion characteristics	No leakage or corrosion of the commercial packaging was observed after storage at 14 days at 54°C. No change in color of the formulation was observed after storage at 14 days at 54°C.	A	497454-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W =Waiver request, NA = Not applicable, I = In progress U = Upgradeable

DP BARCODE No.: D 430931; FILE SYMBOL No: 91090-L; PRODUCT NAME: Neove Spot On #003 for Cats; DECISION No.: 510746; PC Code(s): 105402, 129121; ACTION CODE: R315; FOOD Use: No; COMPANY: Shanghai Neway Animal Health Co., Ltd

#### CONCLUSIONS:

CITAB has reviewed the product chemistry data submitted/cited for the end-use product and has concluded that:

**A. Substantial similarity to the cited product (Reg. EPA Reg. No. from Product chemistry point of view**

- ☐ Similar
- ☐ Not similar,
- ☐ Identical
- ☐ Not identical
- ☒ Not applicable

**B. Confidential Statement of formula**

1. Basic CSF (dated 10/21/15)
  - ☒ Acceptable
  - ☐ Not Acceptable
  - ☐ Not ApplicableIf not acceptable provide the reasons
2. Alternate CSF #1
  - ☐ Acceptable - #1
  - ☐ Not Acceptable
  - ☒ Not ApplicableIf not acceptable give reasons

#### Group A Product Chemistry Data

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Acceptable with the exception of Guideline(s): (provide the guideline number & explain)
- ☐ Not required
- ☐ Data cited

**C. Group B Product chemistry data**

- ☒ Acceptable
- ☐ Not acceptable
- ☐ Not required
- ☐ Data cited

#### Product Label/Draft Label

Recommendations – Yes ☒; No ☐

If yes, give recommendations below:

1. Since the product was determined to react with oxidizing agents the registrant is recommended to add the following statement under the heading Physical and Chemical hazards on the label.  
"Do not mix or allow coming in contact with water. Hazardous chemical reaction may occur".



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

Office of Pesticide Programs  
Registration Division (7505P)

May 20, 2016

MEMORANDUM      DER for acute toxicity studies for Neove Spot On #003 for Cats

Subject:      Name of the Product      Neove Spot On #003 for Cats  
                 EPA File Symbol:      91090-L  
                 DP Barcode      430946  
                 Decision No      510746  
                 Action Code:      R315  
                 PC Codes:      105402; 129121

From:      Princess Campbell, DVM, MS, DACVPM  
                 CITAB

Thru:      Masih Hashim, PhD., Toxicology Team Leader  
                 CITAB  
                 Registration Division (7505P)

To:      Kable Davis/Timothy Ciarlo RM 03  
                 Invertebrate- Vertebrate Branch I  
                 Registration Division (7505P)

Applicant:      SHANGHAI NEWAY ANIMAL HEALTH CO. LTD  
                 Gig Harbor, WA 98332

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by weight</u>
Fipronil	9.8
S-methropene	11.8
<u>Other Ingredient(s):</u>	<u>78.4</u>
Total:	100.0

ACTION REQUESTED:



“Please review the associated acute tox data for 91090-L and determine if they are acceptable for product registration. Please note that the registrant is requesting a waiver for acute inhalation (see MRID 49745404) and is citing the remaining tox studies”.

#### BACKGROUND:

Shanghai Neway Animal Health Co., LTD has cited five acute toxicity data, (MRIDs 44942004-08), to support the registration of 91090-L, an insecticide. These studies have been previously reviewed by TRB (memorandum dated December 12, 1999 for 65331-U) and were classified as acceptable. The registrant has submitted a data waiver request, MRID49745404, and has stated on page 6 of the request that “inhalation is not expected to be a significant route of exposure because of the use pattern, a spot-on application to cats. The actual containers are child resistant packages that contain an applicator which is fully enclosed in a foil backed blister package. Each applicator holds less than 0.02 fluid ounces of formulation (actual contents are 0.017 fl. oz.)....”

The registrant also noted that EPA has waived the requirement for inhalation toxicity for similar spot-on products. TRB recommends for granting this waiver based on the use pattern. In a former review dated February 22, 2013, for a similar product, 88052-RG, based on the low acute toxicity of the cited studies.

Deficiencies: All studies are in compliance with EPA guidelines; any deficiency is not significant and does not affect the outcome of the study.

GLP: Yes.

#### RECOMMENDATIONS/FINDINGS:

All five cited studies have been classified as acceptable. EPA grants the waiver request.

The acute toxicity profile for the proposed product Neove Spot On for Cats, EPA File Symbol 91090-L, derived from the cited product (memorandum: Hashim, M., D261562 dated December 12, 1999) is as follows:

*Acute oral toxicity	III	cited	EPA Reg. No. 65331-U
Acute dermal toxicity	IV	cited	EPA Reg. No. 65331-U
Acute inhalation toxicity	-	Waived	MRID 49745404
Primary eye irritation	IV	cited	EPA Reg. No. 65331-U
Primary skin irritation	IV	cited	EPA Reg. No. 65331-U
Dermal sensitization	Neg.	cited	EPA Reg. No. 65331-U

\*Please note that the acute oral dosage is incorrectly listed in the December 12, 1999 memorandum as mg/kg instead of g/kg.

**PRODUCT NAME: Neove Spot On #003 for Cats**

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD: CAUTION**

**Hazards to Humans and Domestic Animals:**

Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

## Ciarlo, Timothy

---

**From:** Jennifer Yentel <Jennifer@PyxisRC.com>  
**Sent:** Thursday, July 28, 2016 4:38 PM  
**To:** Ciarlo, Timothy  
**Cc:** Davis, Kable; IVB1; Janelle Kay  
**Subject:** RE: 91090-L Label Comments  
**Attachments:** 91090-L.20160728.Neove Spot On #003 for Cats (ver 3) (clean).pdf; 91090-L.20160728.Neove Spot On #003 for Cats (ver 3) (tracked changes).pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Hi Tim, Attached you will find the revised label for 91090-L. The clean and tracked-changes versions are attached. Let me know if you need anything else.

Best regards,  
Jennifer

Jennifer Yentel  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. Ct. NW  
Gig Harbor, WA 98332  
(T): 1-253-853-7369  
(F): 1-253-853-5516  
(E): [Jennifer@PyxisRC.com](mailto:Jennifer@PyxisRC.com)

**From:** Ciarlo, Timothy [mailto:Ciarlo.Timothy@epa.gov]  
**Sent:** Thursday, July 28, 2016 3:55 PM  
**To:** Jennifer Yentel <Jennifer@PyxisRC.com>  
**Cc:** Davis, Kable <Davis.Kable@epa.gov>; IVB1 <IVB1@epa.gov>; Janelle Kay <Janelle@PyxisRC.com>  
**Subject:** RE: 91090-L Label Comments

Hi Jennifer,

I have similar comments for -L. Please see the attached PDF and respond with a revised label. Let me know if you have any questions.

Regards,

Tim Ciarlo  
Entomologist  
Environmental Protection Agency  
OCSPP/OPP/RD/IVB1  
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**From:** Jennifer Yentel [<mailto:Jennifer@PyxisRC.com>]  
**Sent:** Thursday, July 28, 2016 1:00 PM *Resubmission #1*  
**To:** Ciarlo, Timothy <[Ciarlo.Timothy@epa.gov](mailto:Ciarlo.Timothy@epa.gov)>  
**Cc:** Davis, Kable <[Davis.Kable@epa.gov](mailto:Davis.Kable@epa.gov)>; IVB1 <[IVB1@epa.gov](mailto:IVB1@epa.gov)>; Janelle Kay <[Janelle@PyxisRC.com](mailto:Janelle@PyxisRC.com)>  
**Subject:** RE: 91090-L Label Comments

Hi Tim,

Attached please find the revised label for Neove Spot On #003 for Cats (EPA File Symbol No. 9190-L). I've attached a clean version of the label as well as a tracked changes copy. I slightly modified the additional language that you requested in the Physical or Chemical Hazards Section from "Do not mix or allow coming in contact with oxidizing agents. Hazardous chemical reaction may occur." to "Do not mix or allow to come into contact with oxidizing agents. Hazardous chemical reaction may occur.". The modification is grammatical in nature and is only meant to make the statement a little clearer to the end-user. If you have any questions or if there are any additional issues with this label, please let me know.

Regards,  
Jennifer

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**From:** Ciarlo, Timothy [<mailto:Ciarlo.Timothy@epa.gov>]  
**Sent:** Wednesday, July 27, 2016 4:34 PM  
**To:** Janelle Kay <[Janelle@PyxisRC.com](mailto:Janelle@PyxisRC.com)>; Jennifer Yentel <[Jennifer@PyxisRC.com](mailto:Jennifer@PyxisRC.com)>  
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**Subject:** 91090-L Label Comments

Hi Janelle and Jennifer,

I've completed the initial label review for 91090-L. Please see the attached PDF for my comments/edits. If you have any questions or concerns, please let me know. I have the pre-decisional due date for this action as 8/8/16. I'll stand by for a revised label.

Regards,

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